DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “tie layer between the ring and the elastic portion of the tip" as claimed in claim 39 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 40 recite “an elongate tubular member having a proximal end and a distal end with a guide wire receiving lumen extending therethrough” and “tubular member having a proximal end, a distal end, and a guidewire lumen extending therethrough”. This claim language requires that the guidewire lumen extend from the proximal end to the distal end. However, later in each claim is recited "a tip ... having a distal end, a proximal end and a tip lumen therethrough". This claim language defines a tip lumen, which has already been claimed as a guidewire lumen, which gives rise to confusion and in effect claiming the same structure twice, but with different names.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 12, 16, 17, & 19-23, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (US 2003/0125751) in view of Muni et al. (US Patent No. 5,316,706) and further in view of Van Tassel et al. (US Patent No. 4,531,943). Griffin discloses the device substantially as claimed including a medical device comprising: a guidewire (Fig. 6a discloses an embodiment with a guidewire (21)) having a first diameter (diameter of the guidewire 21) and a distal stop having a second diameter greater than the first diameter (distal stop is 29 which has a different diameter; also see paragraph [0187]); an elongate tubular member (Figs. 49 and 50, 210) having a proximal end (near 2) and a distal end (near 31) with a guide wire receiving lumen (7) extending therethrough, a distal portion of the guidewire lumen having an inner diameter of substantially the same magnitude as the first diameter (portion 13 clearly has a lumen within it that snugly encompasses the diameter of the guidewire); and a tip (the tip beginning at where the portion 13 ends and the tip extends distally until the very distal-most part of 202) disposed at the distal end of the elongate tubular member and having a distal end (near 202), a proximal end (near 5) and a tip lumen therethrough (lumen which 21 passes through), the tip having an elastic portion (portion 31 is an elastic

portion) and a radially inextensible distal portion distal of the elastic portion (202 is distal of elastic portion 31 and is radially in extensible; Figs. 46 and 47 as well as paragraph [0302] and Figs. 37-39 disclose that the distal end of the catheter is made of flexible material, designed to deform upon compression and contact. Furthermore, paragraph [0303] discloses that the radially inextensible ring acts as a stop when contacting the filter. Also see paragraphs [0266], [0267] and [0303] which disclose that portion 31 is a deformable polymeric material but portion 202 is a harder material which acts as a stop when it abuts the stop on the guidewire and prevents the distal end of the catheter from deforming around the stop of the guidewire); wherein the elongate tubular member is slidably disposed on the guidewire such that the distal end of the tip engages against eh distal stop when the elongate tubular member is advanced distally relative to the guidewire (wherein the radially inextensible distal portion is a distal most extremity (the catheter is perfectly capable of performing this function); Figs. 46, 47, 49 and 50 disclose that the very distal tip of 202 is the distal-most extremity of the catheter), wherein the tip is configured to invert proximally into the lumen (it is the examiner's position that the tip is perfectly capable of inverting proximally into the lumen if enough pressure is applied to the tip when it abuts an object such as the guidewire stop. The tip is capable of such a deformation if the right conditions are present, and therefore is capable of meeting this functional language). Griffin, however, does not disclose that the tip comprises an amorphous polymer or that the radially inextensible distal portion comprises a locally crystalline section thereof or that the distal end of the tip is configured to invert proximally into the tip lumen upon engaging the distal stop.

Muni, however, discloses a catheter and method of making a catheter, in which softer sections are made from amorphous polymers and the hardened sections are made from crystalline sections (col. 3, lines 33-39 disclose the relationship between crystallinity and hardness, while col. 3, line 60 through col. 4, line 29 disclose that the crystalline and amorphous sections can be altered so that the catheter can have any pattern of hardness and softness. Specifically, col. 4, lines 18-22 disclose that catheter does not have to be limited to the stiff portion being the body portion and the soft portion being the tip, and also discloses that the crystallinity may be "varied in any of a plurality of zones throughout the length" thus indicating that many different portions can be soft or crystallized, depending on what is preferred. Therefore it would have been obvious to one of ordinary skill in the art, due to this teaching to have made a portion distal of the amorphous portion of the tip, crystalline). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Griffin with the method and pattern of hardening catheter sections by altering crystallinity, as taught by Muni, in order to provide another source of a hardened tip for the catheter, especially since Muni discloses that the regions of crystalline and the softer amorphous polymer regions can be varied.

Van Tassel discloses a similar catheter (Figs. 4 and 5) and further discloses that the shape of the distal tip of the catheter is such that when it contacts a surface it allows the distal end of the tip to invert proximally into the tip lumen (Fig. 5). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Griffin in view of Muni with the shape of the distal tip which allows inversion

into the tip lumen, as taught by Van Tassel, as this would have involved a change in shape of the tip and a change in shape is generally recognized as being within the level of ordinary skill in the art.

In reference to claim 12, Griffin discloses that the radially inextensible distal portion comprises a ring having a lumen therethrough (Figs. 49 and 50 disclose that 202 has a lumen through it).

In reference to claims 16 and 17, as defined by MPEP 2113, product by process claims are not limited to the recited steps, only the structure implied by the steps. Therefore the distal portion is anticipated by Griffin.

In reference to claim 19, Griffin discloses that the radially inextensible distal portion comprises a non-compliant plastic band (paragraph [0303]).

In reference to claim 20, Griffin discloses that the tip further comprises a flexible portion proximate the radially inextensible distal portion (portion 31 is more flexible than portion 202; see paragraph [0303]).

In reference to claim 21, Griffin discloses that the flexible portion is proximal of the radially inextensible distal portion (portion 31 is proximal to 202), wherein the flexible portion tapers from a first outer diameter at a first location along the tip to a second outer diameter less than the first outer diameter at a second location along the tip distal of the first location (see Figs. 49 and 50 and the marked-up version of Fig. 49 at the end of the office action).

In reference to claim 22, Griffin discloses that at the first location along the tip, the tip has a first thickness and a first inner diameter, and wherein at the second

location along the tip distal of the first location, the tip has a second thickness less than the first thickness and a second inner diameter greater than the first inner diameter (see Fig. 49 and the marked up version of Fig. 49 at the end of the office action).

In reference to claim 23, Griffin discloses that the flexible portion comprises an inner surface concave in a first plane normal to a longitudinal axis and a second plane normal to the first plane (Fig. 49).

In reference to claim 38, Van Tassel discloses that the tip lumen comprises a cavity within the tip, wherein the cavity forms a concave hollow that is larger in diameter than the inner diameter of the guidewire lumen (Figs. 4 and 5 hollow 27).

In reference to claim 39, Griffin discloses a tie layer between the ring and the elastic portion of the tip (the boundary between 202 and 31 will have a tie layer if the material is heated during bonding of 202 and 21 as the heating will cause a blending of the materials at the junction).

Claims 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (US 2003/0125751) in view of Muni et al. (US Patent No. 5,316,706) and further in view of Van Tassel et al. (US Patent No. 4,531,943). Griffin discloses the device substantially as claimed including a medical device comprising: a guidewire (Fig. 6a discloses an embodiment with a guidewire (21)) having a first diameter (diameter of the guidewire 21) and a distal stop having a second diameter greater than the first diameter (distal stop is 29 which has a different diameter; also see paragraph [0187]);

an elongate tubular member (Figs. 49 and 50, 210) having a proximal end (near 2) and a distal end (near 31) with a guide wire receiving lumen (7) extending therethrough, a distal portion of the guidewire lumen having an inner diameter of substantially the same magnitude as the first diameter (portion 13 clearly has a lumen within it that snugly encompasses the diameter of the guidewire); an integrally formed tip (the tip beginning at where the portion 13 ends and the tip extends distally until the very distal-most part of 202) disposed at the distal end of the elongate tubular member and having a distal end (near 202), disposed at the distal end of the elongate tubular member and having a proximal end (near 5) and a tip lumen therethrough (lumen which 21 passes through), in fluid communication with the guidewire lumen; wherein the tip having an elastic portion (portion 31 is an elastic portion) and a radially inextensible distal portion distal of the elastic portion (202 is distal of elastic portion 31 and is radially in extensible; Figs. 46 and 47 as well as paragraph [0302] and Figs. 37-39 disclose that the distal end of the catheter is made of flexible material, designed to deform upon compression and contact. Furthermore, paragraph [0303] discloses that the radially inextensible ring acts as a stop when contacting the filter. Also see paragraphs [0266], [0267] and [0303] which disclose that portion 31 is a deformable polymeric material but portion 202 is a harder material which acts as a stop when it abuts the stop on the guidewire and prevents the distal end of the catheter from deforming around the stop of the guidewire); wherein the elongate tubular member is slidably disposed on the guidewire such that the distal end of the tip engages against eh distal stop when the elongate tubular member is advanced distally relative to the guidewire (wherein the radially inextensible

distal portion is a distal most extremity (the catheter is perfectly capable of performing this function); Figs. 46, 47, 49 and 50 disclose that the very distal tip of 202 is the distal-most extremity of the catheter), wherein the tip is configured to invert proximally into the lumen (it is the examiner's position that the tip is perfectly capable of inverting proximally into the lumen if enough pressure is applied to the tip when it abuts an object such as the guidewire stop. The tip is capable of such a deformation if the right conditions are present, and therefore is capable of meeting this functional language). Griffin, however, does not disclose that the tip comprises an amorphous polymer or that the radially inextensible distal portion comprises a locally crystalline section thereof or that the distal end of the tip is configured to invert proximally into the tip lumen upon engaging the distal stop.

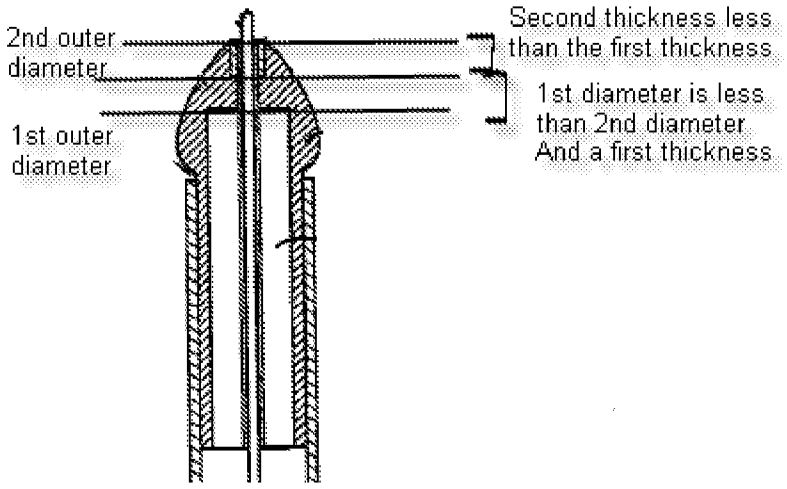
Muni, however, discloses a catheter and method of making a catheter, in which softer sections are made from amorphous polymers and the hardened sections are made from crystalline sections (col. 3, lines 33-39 disclose the relationship between crystallinity and hardness, while col. 3, line 60 through col. 4, line 29 disclose that the crystalline and amorphous sections can be altered so that the catheter can have any pattern of hardness and softness. Specifically, col. 4, lines 18-22 disclose that catheter does not have to be limited to the stiff portion being the body portion and the soft portion being the tip, and also discloses that the crystallinity may be "varied in any of a plurality of zones throughout the length" thus indicating that many different portions can be soft or crystallized, depending on what is preferred. Therefore it would have been obvious to one of ordinary skill in the art, due to this teaching to have made a portion distal of the

amorphous portion of the tip, crystalline). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Griffin with the method and pattern of hardening catheter sections by altering crystallinity, as taught by Muni, in order to provide another source of a hardened tip for the catheter, especially since Muni discloses that the regions of crystalline and the softer amorphous polymer regions can be varied.

Van Tassel discloses a similar catheter (Figs. 4 and 5) and further discloses that the shape of the distal tip of the catheter is such that when it contacts a surface it allows the distal end of the tip to invert proximally into the tip lumen (Fig. 5). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Griffin in view of Muni with the shape of the distal tip which allows inversion into the tip lumen, as taught by Van Tassel, as this would have involved a change in shape of the tip and a change in shape is generally recognized as being within the level of ordinary skill in the art.

In reference to claim 41, Van Tassel discloses that the inverted tip stores energy that is released when the tip returns to an everted state, and the stored energy theists in peeling the tip off of the distal stop (Figs. 4 and 5).

In reference to claim 42, Van Tassel discloses that releasing the stored energy provides tactile feedback to an operator of the medical device (Figs. 4 and 5).



Response to Arguments

Applicant's arguments with respect to claims 9, 12, 16, 17, 19, 21-23, 38-42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767